

What is claimed is:

1. An oral dosage formulation, comprising:
a therapeutically effective amount of lipoic acid;
a therapeutically effective amount of a lipid soluble thiamine; and
an excipient material.
2. The formulation of claim 1, wherein the lipoic acid comprises a racemic mixture of enantiomers.
3. The formulation of claim 1, wherein the lipoic acid comprises 80% or more R-(+) enantiomer of lipoic acid with 20% or less being the L-(-) enantiomer.
4. The formulation of claim 1, wherein the lipoic acid comprises a substantially pure R-(+) enantiomer of lipoic acid.
5. The formulation of claim 1, wherein the formulation is characterized by releasing a first portion of the lipoic acid and the lipid soluble thiamine sufficient to obtain a therapeutic level at a first rate substantially equivalent to a release rate of a quick release formulation and releasing a remaining portion of the lipoic acid at a controlled rate which is below a release rate of a quick release formulation.
6. The formulation of claim 5, wherein the first portion of the lipid soluble thiamine and lipoic acid is from about 10% to about 50% of the lipid soluble thiamine and lipoic acid in the formulation.
7. The formulation of claim 6, wherein the first portion of the lipid soluble thiamine and lipoic acid is from about 20% to about 30% of the lipid soluble thiamine and lipoic acid in the formulation.

8. The formulation of claim 7, wherein the first portion of the lipid soluble thiamine and lipoic acid is about 25% of the lipid soluble thiamine and lipoic acid in the formulation.

9. The formulation of claim 5, wherein the controlled rate maintains the therapeutic level of both the lipid soluble thiamine and the lipoic acid for a period which is 10% or more longer as compared to a quick release formulation.

10. The formulation of claim 5, wherein the controlled rate maintains the therapeutic level of both the lipid soluble thiamine and the lipoic acid for a period which is 50% or more longer as compared to a quick release formulation.

11. The formulation of claim 5, wherein the controlled rate maintains the therapeutic level of both the lipid soluble thiamine and the lipoic acid for a period which is 100% or more longer as compared to a quick release formulation.

12. The formulation of claim 5, wherein the controlled rate maintains the therapeutic level of both the lipid soluble thiamine and the lipoic acid for a period which is 200% or more longer as compared to a quick release formulation.

13. The formulation of claim 1, further comprising an orally active antidiabetic chosen from a sulfonylurea, a biguanide and a thiazolidinedione.

14. The formulation of claim 1, further comprising metformin hydrochloride.

15. The formulation of claim 1, wherein the lipoic acid is present as a racemic mixture of L- and R- enantiomers and the therapeutic level is maintained over a period of four hours or more.

16. The formulation of claim 1, wherein the lipoic acid is present as substantially pure R-(+) enantiomer and the therapeutic level is maintained over a period of

four hours or more and further wherein the lipid soluble thiamine is chosen from benfotiamine and prosultamine.

17. The formulation of claim 5, wherein the controlled rate is a rate of about 25% or less per hour slower than a quick release formulation.

18. The formulation of claim 5, wherein the controlled rate is a rate of about 50% or less per hour slower than a quick release formulation.

19. A method of treatment, comprising:
orally administering to a patient a formulation comprising a lipid soluble thiamine and lipoic acid; and

repeating the administering on three or more consecutive days thereby maintain a therapeutic level of both the lipid soluble thiamine and lipoic acid in the patient's circulatory system over a therapeutically effective period of time on three or more consecutive days.

20. The method of claim 19, wherein the therapeutic level is maintained over a period of time which is 10% or more than that obtained with a quick release formulation and further wherein the repeating is over thirty or more consecutive days.

21. The method of claim 19, wherein the therapeutic level is maintained over a period of time which is 100% or more than that obtained with a quick release formulation and further wherein the repeating is over thirty or more consecutive days.

22. The method of claim 19, wherein the therapeutic level of lipoic acid is a level sufficient to obtain measurable vasodilation in a human patient.

23. The method of claim 19, wherein the therapeutic level is a level sufficient to obtain a measurable reduction in a human patient's serum glucose level.

24. A method of reducing a human patient's serum glucose level, comprising:

administering a therapeutically effective amount of an orally active antidiabetic selected from the group consisting of a sulfonylurea, a biguanide and a thiazolidinedione; and administering an oral formulation of a lipid soluble thiamine and lipoic acid.

25. The method of claim 24, further comprising:
repeatedly administering the antidiabetic and the formulation of lipid soluble thiamine and lipoic acid on a daily basis for five or more days.

26. The method of claim 21, wherein the antidiabetic is metformin hydrochloride which is administered in an amount in a range of about 500 mg to about 1,000 mg per day.

27. A method of treating a human patient, comprising:
administering to a human patient a biphasic formulation of lipid soluble thiamine and lipoic acid which formulation is characterized by maintaining a therapeutic level of the lipid soluble thiamine and lipoic acid in the patient's circulatory system over a period of time greater than that obtained with a quick release formulation; and
repeating the administering on three or more consecutive days thereby maintain a therapeutic level of both the lipid soluble thiamine and lipoic acid in the patient's circulatory system over a therapeutically effective period of time on three or more consecutive days.

28. A method of treating diabetes mellitus, comprising the steps of:
orally administering to a diabetic human patient a therapeutically effective amount of a formulation comprising lipoic acid and a lipid soluble thiamine; and
repeating the administering on three or more consecutive days thereby maintain a therapeutic level of both the lipid soluble thiamine and lipoic acid in the patient's circulatory system over a therapeutically effective period of time on three or more consecutive days.

29. The method of claim 28, wherein the lipoic acid is a racemic mixture of enantiomers.

30. The method of claim 28, wherein the lipoic acid is a substantially pure R-(+) enantiomer of lipoic acid.

31. The method of claim 28, further comprising:
orally administering metformin hydrochloride in an amount in a range of from about 500 mg to about 1,000 mg per day; and
repeating the administration on three or more consecutive days.